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| 09/997,023   | 11/30/2001  | R. Sam Niedbala      | 044170-5034         | 6134             |
| 22204  | 7590        | 03/18/2004           | EXAMINER            |                  |
| NIXON PEABODY, LLP<br>401 9TH STREET, NW<br>SUITE 900<br>WASHINGTON, DC 20004-2128 |             |                      | ALEXANDER, LYLE     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1743                |                  |

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,023

Applicant(s)

NIEDBALA ET AL.

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25, 46-52 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25, 46-52 and 64-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,5-7, 10,12-13 and 64-67 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Patel et al. or Bunce et al.

Patel et al. teach a device(10) that has ports(12) that permit fluid to the bottom of the device. There is a first piece of bibulous material(32),and a second piece of bibulous material(34) and a piece of liquid expandable material(22). When material(28) expands, materials(32) and (34) are in fluid contact with one another. Material(28) expands as a result of fluid through port mark(20). Material(28) has been read on the claimed “expandable collection member”. Material(34) can contain a reagent for analysis of a reagent.

Bunce et al. teach many different configurations that read on the instant claims. Figure 4 is exemplary and teaches a liquid transfer device comprising a holding a portion (70d) having first and second ends, a retaining portion(32) attached to the holding portion, and expandable collection member(23d) having a first and second size and reagents(32d) to detect the analyte of interest.

Claims 1,3,7-8,10,12-13, 64-66 and 14-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schmitz(USP 3,713,775).

Schmitz teaches in figures 2-3 a pipette(51) having a first and second end. The interior of the pipette retains a sample and plunger(54) has been read on the claimed "expandable collection member" having a first and second size. The pipette tip(55) has been read on the claimed "discharge member" and place the sample in curette(36) containing reagents(210).

Claims 1-3,5-8,10,12-13,46-51 and 64-66 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shapiro(USP 4,750,373), Hydo(USP 4,036,064) or Magnussen et al.(USP 5,364,596).

These references teach sample collection means having a plunger with multiple positions and stops, which have been read on the claimed first, and second holding positions.

#### ***Allowable Subject Matter***

Claims 4,9 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed 12/19/03 have been fully considered but they are not persuasive.

Applicants state Patel fails to teach (1) a holder portion .... (2) a retaining portion .... and (3) an expandable collector member... . Patel et al. teach a housing(11) that has been read on claimed element(1), a compressible member(24) that has been read

on claimed element(2) and a expandable member(22) that has been read on the claimed element(3). The claimed first and second sizes have been read on the dry and wetted states of Patel.

Applicants state Bunce et al. fails to teach (1) a holder portion .... (2) a retaining portion .... and (3) an expandable collector member... . Bunce et al. teach a holding portion(70d) that has been read on claimed element(1), a retaining portion(32) that has been read on claimed element(2) and a expandable member(23d) that has been read on the claimed element(3). The claimed first and second sizes have been read on the dry and wetted states of Bunce et al. Applicants state portion(70d) is described as a channel and cannot be read on the claimed holding portion. In the absence of better defining what structure is intended by "holding portion", the Office maintains portion(70d) holds the device meeting the claims.

Applicants state Schmitz et al. fails to teach (1) a holder portion .... (2) a retaining portion .... and (3) an expandable collector member... . Schmitz teaches in figures 2-3 a pipette(51) having a first and second end. The interior of the pipette retains a sample and plunger(54) has been read on the claimed "expandable collection member" having a first and second size. The pipette tip(55) has been read on the claimed "discharge member" and place the sample in curette(36) containing reagents(210).

Applicants state Shapiro(USP 4,750,373), Hydo(USP 4,036,064) and Magnussen et al.(USP 5,364,596) fail to teach (1) a holder portion .... (2) a retaining portion .... and (3) an expandable collector member... . These references teach sample collection means having a plunger with multiple positions and stops, which have been

read on the claimed first and second holding positions as well as the expandable collector.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander  
Primary Examiner  
Art Unit 1743